Federal Court of Appeal | Cour d'appel fédérale

Date: 20250618

Docket: A-290-23

Citation: 2025 FCA 119

CORAM: **RENNIE J.A.**
WOODS J.A.
LASKIN J.A.

BETWEEN:

JEFF TOTH, ADELE PHILLIPS, ALEX DOLEY, ALLISON PRINSEN, ANTHONY DI VIRGILIO, BARBARA FEHLAU, BARBARA GRIFFIN, CHRISTINE DENNSTEDT, DALE TRIMBLE, DANIELLE SCHROEDER, DANUSIA KANACHOWSKI, DAPHNE LOBB, GRAHAM BERGSTRA, GREGORY COHEN, HILLARY MCBRIDE, JENNA FLETCHER, JILL KOEHLER, JOHN GYRA, JONATHAN WIESER, KEYANNA EHSANI, KYLE GREENWAY, LAURIE SCHULZ, LISA FREDE, MYRNA MARTIN, RICHARD TATOMIR, SALLYJANE BODNAR, SARAH HOFFMAN, STACY SMITH, VALENTINA CHICHINIOVA, VANATHY PARANTHAMAN, AAMIR SUBHAN, AMANDA GRINTER, ANNE-MARIE ARMOUR, BETH TROTTER, BRODIN ANDERSON, BRYCE KOCH, CLAIRE WEISS, DAYNA MYLES, DOROTHY GAMBLE, ELINOR BAZAR, ELIZABETH BLEAKLEY, GORDON REID, JANE HARRISON, JANIE BROWN, JEAN-FRANÇOIS STEPHAN, JENNIFER NAGEL, JULIA MACARTHUR, KATHLEEN HERBINSON, KERRY CHUTTER, LORRAINE REIMER, MARILYN CHOTEM, MICHAEL SHEPPARD, NATHAN TORTI, NIKHITA SINGHAL, PARVEEN SIHOTA, RAJVEER SOOS, RICHARD MINERS, SCOTT KOURI, SHAUNA SUTHERLAND, STEPHANIE MARCHAL, STEVEN GRIFFITH-COCHRANE, TAMARA SMITH, TRACY LOWE, TRINA WOODS, YASSIE PIRANI, DANA SIMARD, MICHAEL SIMARD, ANNE KWASNIK-KRAWCZYK, GRANT HUTCHINSON, JULIEN THIBAULT LÉVESQUE, SUSAN MCAFEE, LARA ELLISON, ELANA ANGUS, KATHERINE MARYKUCA, SHANNON MCKENNEY, JESSICA PIETRYSZYN, JEREMY MOORE, MATTHEW HUNTER, KATHLEEN WESTLAKE, WILLIAM ALVES, MELISSA SLADE and THERAPSIL

Appellants

and

MINISTER OF MENTAL HEALTH AND ADDICTIONS AND ASSOCIATE MINISTER OF HEALTH

Respondent

Heard at Ottawa, Ontario, on November 6, 2024.

Judgment delivered at Ottawa, Ontario, on June 18, 2025.

REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: WOODS J.A.
LASKIN J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20250618

Docket: A-290-23

Citation: 2025 FCA 119

CORAM: **RENNIE J.A.**
WOODS J.A.
LASKIN J.A.

BETWEEN:

JEFF TOTH, ADELE PHILLIPS, ALEX DOLEY, ALLISON PRINSEN, ANTHONY DI VIRGILIO, BARBARA FEHLAU, BARBARA GRIFFIN, CHRISTINE DENNSTEDT, DALE TRIMBLE, DANIELLE SCHROEDER, DANUSIA KANACHOWSKI, DAPHNE LOBB, GRAHAM BERGSTRA, GREGORY COHEN, HILLARY MCBRIDE, JENNA FLETCHER, JILL KOEHLER, JOHN GYRA, JONATHAN WIESER, KEYANNA EHSANI, KYLE GREENWAY, LAURIE SCHULZ, LISA FREDE, MYRNA MARTIN, RICHARD TATOMIR, SALLYJANE BODNAR, SARAH HOFFMAN, STACY SMITH, VALENTINA CHICHINIOVA, VANATHY PARANTHAMAN, AAMIR SUBHAN, AMANDA GRINTER, ANNE-MARIE ARMOUR, BETH TROTTER, BRODIN ANDERSON, BRYCE KOCH, CLAIRE WEISS, DAYNA MYLES, DOROTHY GAMBLE, ELINOR BAZAR, ELIZABETH BLEAKLEY, GORDON REID, JANE HARRISON, JANIE BROWN, JEAN-FRANÇOIS STEPHAN, JENNIFER NAGEL, JULIA MACARTHUR, KATHLEEN HERBINSON, KERRY CHUTTER, LORRAINE REIMER, MARILYN CHOTEM, MICHAEL SHEPPARD, NATHAN TORTI, NIKHITA SINGHAL, PARVEEN SIHOTA, RAJVEER SOOS, RICHARD MINERS, SCOTT KOURI, SHAUNA SUTHERLAND, STEPHANIE MARCHAL, STEVEN GRIFFITH-COCHRANE, TAMARA SMITH, TRACY LOWE, TRINA WOODS, YASSIE PIRANI, DANA SIMARD, MICHAEL SIMARD, ANNE KWASNIK-KRAWCZYK, GRANT HUTCHINSON, JULIEN THIBAULT LÉVESQUE, SUSAN MCAFEE, LARA ELLISON, ELANA ANGUS, KATHERINE MARYKUCA, SHANNON MCKENNEY, JESSICA PIETRYSZYN, JEREMY MOORE, MATTHEW HUNTER, KATHLEEN WESTLAKE, WILLIAM ALVES, MELISSA SLADE and THERAPSIL

Appellants

and

MINISTER OF MENTAL HEALTH AND ADDICTIONS AND ASSOCIATE MINISTER OF HEALTH

Respondent

REASONS FOR JUDGMENT

RENNIE J.A.

Overview

[1] Psilocybin is a psychoactive compound found in certain mushrooms. It is classified as a drug under the *Food and Drugs Act*, R.S.C., 1985, c. F-27. It is also listed as a controlled substance under Schedule III of the *Controlled Drugs and Substances Act*, S.C. 1996 c. 19 (CDSA, the Act), and its possession is criminally prohibited by section 4 unless otherwise authorized. The Minister of Health has discretion under subsection 56(1) of the Act to grant exemptions from the application of section 4 where possession of a prohibited substance is necessary for medical or scientific purposes or is otherwise in the public interest.

[2] Psilocybin-assisted psychotherapy (PSAP) is the medically-supervised consumption of psilocybin. PSAP has been used for treatment or management of serious medical conditions, including end-of-life distress and treatment-resistant depression.

[3] In February 2022, 73 health care practitioners (HCPs) submitted requests to Health Canada under subsection 56(1) of the CDSA for exemptions from section 4 of the Act to allow them to possess, transport, and consume psilocybin mushrooms for a PSAP training program provided by TheraPsil. TheraPsil is a not-for-profit patient advocacy corporation dedicated to helping Canadians access PSAP. The 73 HCPs include doctors, psychologists, nurses, social workers, counsellors and other regulated health care professionals.

[4] TheraPsil connects prospective patients with qualified HCPs that have gone through TheraPsil's training program. TheraPsil's program requires HCPs to undergo "experiential training", wherein they personally consume psilocybin to experience the altered state of consciousness patients experience during PSAP. The HCPs assert that such experiential training is necessary for them "to deliver the safest and most effective treatment to their patients," for without it patients are exposed "to more risk and…lower odds of a successful outcome."

[5] In January 2022, a delegate of the Minister of Mental Health and Addictions and Associate Minister of Health (the Minister) sent notices of intent to refuse the requests on the basis that the appellants could access psilocybin through a clinical trial, rendering an exemption unnecessary. Although the CDSA is administered by the Minister of Health, Order-in-Council 2022-0549, which was effective May 26, 2022, transferred the powers, duties, and functions under the Act from the Minister of Health to the Minister of Mental Health and Addictions and Associate Minister of Health.

[6] In response to the notices of intent to refuse, the appellants made submissions to the Minister arguing that a clinical trial was neither a realistic nor ethical alternative. They relied on scientific and medical articles which they contended supported the view that experiential training was necessary for effective and safe PSAP. The legal thrust of their submissions was that the Minister's denial of the requests would violate the HCPs' rights under section 7 of the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 (*Charter*).

[7] This brings me to the second group of appellants in this appeal.

[8] Eight individuals who were on TheraPsil's waitlist for assessment of their suitability for PSAP supported the judicial review application. The Federal Court referred to them as the "patient applicants" and I will use the term "patient appellants" to be consistent with the description in the Federal Court's reasons; but I do so with caution. First, there is no doctor-patient relationship between the HCPs and any of the patient appellants and, second, the word "patient" is misleading in association with some of the professions concerned, such as social workers. Further, none of the eight patient appellants made requests for their own exemptions under subsection 56(1). I will return to this later in the discussion of the standing of the patient appellants and whether section 7 of the *Charter* is engaged by the Minister's decisions.

[9] The Minister's final decisions (Decisions) consisted of substantively identical three-page letters sent to each of the 73 HCPs and eight patient appellants, reiterating the reasoning of the notices of intent to refuse. The Decisions found the exemptions unnecessary because there was an existing "regulatory option" by which access to psilocybin could be obtained. The Minister explained that a clinical trial involving psilocybin, authorized under the *Food and Drug Regulations*, C.R.C., c. 870 (FDR), would protect participants' best interests and facilitate the collection of evidence about the efficacy of psilocybin and PSAP in different contexts. The Minister rejected articles cited by the appellants that the exemptions were necessary to facilitate experiential training, noting that "Health Canada is not aware of peer-reviewed clinical evidence to demonstrate that [HCPs] need to take a psychedelic drug in order to appreciate what the patient experiences."

[10] In their submissions to the Minister in support of the exemptions, the HCPs argued that refusal of the exemptions would violate their section 7 rights, as well as those of the patient appellants. The Decisions make no mention of the arguments with respect to section 7 of the *Charter*.

[11] The HCPs, the patient appellants and TheraPsil applied to the Federal Court for judicial review of the Decisions. The application was dismissed (*Toth et al. v. Minister of Mental Health and Addictions and Associate Minister of Health*, 2023 FC 1283, per Pallotta J. [Reasons]).

[12] Pallotta J. found that the patient appellants did not have standing – private or public interest – and that the HCPs' and patient appellants' *Charter* rights were not engaged by the Decisions. The judge went on to find that, even if they were engaged, the Minister implicitly balanced the *Charter* protections at stake. The judge reasoned that in rejecting the proposition that experiential training was necessary to deliver PSAP, the Minister addressed "the very foundation" of the *Charter* claim. The judge concluded that the clinical trials option provided a suitable means by which the HCPs could access psilocybin and constituted an aspect of a balancing of *Charter* interests against the objectives of the CDSA (Reasons, at paras. 35, 40, 100, 102, 108, 112).

[13] 73 of the 96 HCPs appeal, as do the eight patient appellants. TheraPsil also appeals, in its own right and on behalf of the 23 HCPs who had initially sought subsection 56(1) exemptions and did not appeal their denial.

[14] For the reasons that follow, I would allow the appeal and remit the matter to the Minister for redetermination in accordance with these reasons.

Standard of Review

[15] The first question is whether the Federal Court judge adopted the correct standard of review; the second is whether it was applied correctly (*Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, at para. 46; *Northern Regional Health Authority v. Horrocks*, 2021 SCC 42, at para. 10).

[16] The Supreme Court of Canada issued its decision in *York Region District School Board v. Elementary Teachers' Federation of Ontario*, 2024 SCC 22 (*York*) on June 21, 2024, after the parties' memoranda of fact and law had been filed in this appeal. As *York* provided guidance on the question as to when a decision maker must address *Charter* arguments, counsel provided supplementary submissions to this Court regarding its implications for this appeal.

[17] *York* confirmed the two-step approach for determining *Charter* issues as applied by this Court in *Canadian Broadcasting Corporation v. Canada (Parole Board)*, 2023 FCA 166, at paragraphs 32-34: the standard for determining whether the *Charter* is engaged is correctness, and the standard for assessing the decision maker's weighing of *Charter* values is reasonableness.

[18] Writing for the majority in *York*, Rowe J. held that the question of engagement raises "a constitutional question that requires a final and determinate answer by the courts," and whether the *Charter* does or does not apply is "one that will apply generally and is not dependent on the particular circumstances of the case." *Vavilov*'s category of "other constitutional matters" which rebut the presumptive standard of reasonableness, "should not be unduly narrowed" (*York*¸ at paras. 62, 65 citing *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, at para. 55 [*Vavilov*]).

[19] In light of *York*, the question of whether section 7 of the *Charter* is engaged by the requests is assessed on a correctness standard. If the *Charter* is engaged, whether the Minister adequately balanced the *Charter* interests with the objectives of subsection 56(1) and the scheme of the CDSA is assessed on a reasonableness basis. I agree with Pallotta J. that *Vavilov* and the standard of reasonableness apply to the assessment of the Decisions from an administrative law perspective.

Standing of the Patient Appellants and HCPs

[20] There are four aspects to the standing issue: the private and public interest standing of the HCPs and the private and public interest standing of the patient appellants. It is important to be precise about which party is involved and the nature of their interest.

[21] The Federal Court found that the patient appellants did not have private interest standing. They did not make requests for subsection 56(1) exemptions and thus were not "directly affected

by the matter in respect of which relief is sought" for the purposes of an application for judicial review (Reasons, at paras. 35-39 citing *Federal Courts Act*, R.S.C. 1985, c. F-7, s. 18.1(1)).

[22] This conclusion is irrefutable. The patient appellants did not apply for exemptions nor are they patients of the HCPs who did make applications. As the Federal Court noted, the patient appellants' affidavits state only that, through their own research, they "believe" that they would benefit from PSAP. The patient appellants are not bound by the refusals and are free to make their own requests under subsection 56(1). The refusal to grant the exemptions does not affect the patient appellants' legal rights, impose obligations on them or prejudicially affect them (*Forest Ethics Advocacy Association v. Canada (National Energy Board)*, 2013 FCA 236, at para. 20).

[23] The patient appellants' asserted interests in the judicial review application are indirect. If an HCP completes TheraPsil's training program, the HCP may be placed on a roster and a patient appellant, if assessed as a suitable candidate for PSAP, may choose to undergo PSAP. I agree with the Federal Court judge that this connection is too remote to give rise to private interest standing. The patient appellants' interests arise only through TheraPsil and, even then, only because TheraPsil has made experiential training a requirement of its HCP training.

[24] The Federal Court also found that the patient appellants did not have public interest standing. Again, I agree.

[25] The Federal Court's decision to deny the patient appellants public interest standing was one that was open to it having regard to the governing legal principles and the evidence before it. Decisions on standing are discretionary and entitled to deference on appeal (*Strickland v. Canada (Attorney General)*, 2015 SCC 37, at para. 39). Pallotta J. correctly identified the test for public interest standing from *Canada (Attorney General) v. Downtown Eastside Sex Workers United Against Violence Society*, 2012 SCC 45 (*Downtown Eastside*) and carefully considered the criteria for, and objectives of, standing (Reasons, at paras. 30, 40-43).

[26] *Downtown Eastside* teaches that the test for public interest standing is applied using a "flexible and purposive approach," with none of the factors acting as "hard and fast requirements" or "freestanding, independently operating tests" (at para. 20). More recently, Wagner C.J.C.'s comprehensive review of the law of public interest standing in *Attorney General v. Council of Canadians with Disabilities*, 2022 SCC 27 (*CCD*) instructs that the *Downtown Eastside* factors are to be considered along with the purposes of the law of standing, without assigning weight to any in particular (at paras. 30, 41, 69). Public interest standing plays a key role in helping courts promote access to justice by allowing individuals to advance cases where they are not directly involved nor their own rights infringed (*CCD*, at para. 2).

[27] The patient appellants' evidence details their efforts to access PSAP to treat their serious medical conditions and that these efforts have been thwarted by the lack of physicians trained in PSAP. The patient appellants' claims arguably raise issues of public importance that transcend their immediate interests (*CCD*, at para. 100) – there are over 800 individuals on TheraPsil's waitlist with various medical conditions seeking access to PSAP. I also note the appellants'

submissions that people with disabilities, such as medical conditions for which PSAP may be sought, face financial and personal challenges in bringing litigation. One of the purposes of public interest standing is to promote access to justice for historically disadvantaged groups, including people with disabilities.

[28] The patient appellants say that the Decisions eliminated a pool of 73 HCPs who were seeking qualification in PSAP; once trained, they would diminish the shortage and could improve access to PSAP. The affidavits of the patient appellants discuss the various avenues they have explored to obtain access to PSAP, including through TheraPsil. However, the Federal Court notes that, while the patient appellants want treatment, they "do not express a need for an experientially trained practitioner to provide [PSAP]" (Reasons, at para. 42). Thus, while the patient appellants want treatment, the Federal Court found that they did not explain how they had a genuine stake in the central question in dispute between TheraPsil and the Minister; that is, whether experiential training is necessary for PSAP practitioners.

[29] The patient appellants assert that there is no other way to raise the issue that the shortage of HCPs prevents them from accessing their section 7 *Charter* rights other than by "piggybacking" onto the HCPs' subsection 56(1) exemption requests and being granted public interest standing; otherwise, the Minister's decision will be immunized from challenge (*Canadian Council of Churches v. Canada (Minister of Employment and Immigration),* [1992] 1 S.C.R. 236, 1992 CanLII 116 (SCC), at 250, 252).

[30] I am not persuaded by these arguments.

[31] Prospective decisions will not be immunized from review. There remain effective and focused means to bring the patient appellants' section 7 interests before the Minister. The patient appellants can apply for their own exemptions and, if successful, raise the question of the appropriate course for treatment with their doctors. If the patient appellants are unsuccessful in obtaining exemptions, they can seek judicial review. If there is a shortage of doctors willing to provide treatment, that is an issue between the patient appellants and the provincial licencing authorities and governments. Viewed in this light, the patient appellants' situation is not dissimilar from that of the many Canadians who do not have access to a family physician.

[32] In this regard, it is useful to recall that access to experientially trained HCPs is a problem of TheraPsil's own making, having imposed the requirement for qualification itself. As the Federal Court found, the evidence does not establish that PSAP must be delivered via an experientially trained practitioner and, as we will see, nor does the Minister hold that view. The HCPs themselves recognize this. In their exemption applications, they argue that experiential training is necessary for "optimal" results. There is no evidence that the patient appellants can only access PSAP via an experientially trained provider. It is a preference and, as noted earlier, a "belief" on their part that it would be more successful.

[33] While the patient appellants, if assessed as suitable candidates for PSAP, might benefit from a greater supply of doctors, this is too remote and tangential a connection to the question with which the Minister was seized – whether it is in the public interest that the HCPs themselves receive exemptions so that they may gain experiential training. On this question, the patient appellants do not bring a unique or different perspective than the HCPs; in fact, their

argument mirrors that of the HCPs. As noted by the Federal Court, this point weighs against the patient appellants in the discretionary consideration of whether to grant public interest standing. To this, I would add that there are other, more direct and efficacious means of putting the patient appellants' interests before the Court, such as through their own subsection 56(1) exemption request or, as demonstrated by the decision of the Federal Court in *Lance v. Canada (Attorney General)* 2024 FC 787 (*Lance*), by a request under the Special Access Program.

[34] While there is some merit to the argument that the Federal Court approached public interest standing more as a check-list of mandatory criteria, as opposed to a global weighing or balancing of relevant criteria, this is perhaps more a critique of style than substance. I do not see any palpable and overriding error in the analysis which would justify intervention.

[35] A final point on standing: of the 96 HCPs who submitted requests, 23 did not challenge Health Canada's denial of those applications in the Federal Court and TheraPsil sought judicial review on their behalf. The Minister does not challenge TheraPsil's standing, but Pallotta J. expressed reservations about TheraPsil's standing to advance these challenges, both in its own right and on behalf of the 23 HCPs (Reasons, at para. 44). I share this concern. However, in view of my proposed disposition of this appeal, questions about TheraPsil's standing make no difference to the result.

Whether the Section 7 Rights of the HCPs are Engaged

[36] In their response to the Minister's notices of intent to refuse the requests, the appellants made extensive submissions as to how the section 7 *Charter* rights of the HCPs and the patient appellants would be affected by the Minister's denial of the requests.

[37] The appellants asserted that the HCPs' section 7 liberty rights would be engaged because penal consequences are possible for possession of psilocybin absent exemption (CDSA, ss. 4(1), 4(6)(a)). The HCPs also assert that the section 7 interests of their prospective patients are engaged because denial of the requests restricts the patient appellants' right to make reasonable medical choices and interferes with their security of person by preventing access to safe and effective PSAP.

[38] The record supports the conclusion that the demand for PSAP greatly outweighs the services that the current number of trained HCPs – experientially trained or not – are able to provide. This shortage, the appellants say, deprives prospective patients of access to PSAP, a therapy which may reduce risk of suicide and offers an alternative to medical assistance in dying. Without the exemptions, the HCPs cannot complete their experiential training to provide PSAP, perpetuating this shortage.

[39] The appellants contend that the Decisions must be set aside because they do not respond to the *Charter* arguments and do not balance the appellants' *Charter* interests with section 56 and the objectives of the statutory scheme (*Doré v. Barreau du Québec*, 2012 SCC 12 [*Doré*];

Loyola High School v. Quebec (Attorney General), 2015 SCC 12 [*Loyola*]; *Law Society of British Columbia v. Trinity Western University*, 2018 SCC 32 [*TWU*]).

[40] The *Doré/Loyola/TWU* framework requires a court to examine whether the *Charter* is engaged by an administrative decision. If so, the second step requires an examination of whether the decision maker properly balanced the relevant *Charter* "values" with the statutory provision and its objectives. *York* teaches that the first question, that of engagement, is answered on a correctness basis; the second, whether the balancing was done appropriately, is on a reasonableness basis. Sometimes the second stage is not reached. If *Charter* rights arguments are not considered, it may be that the decision is neither correct nor reasonable:

> …where, as in this case, a Charter protection is squarely raised by a party, the unexplained failure to address whether the Charter was engaged cannot survive reasonableness review. The reasons were not responsive to the question as framed in circumstances where it was called on to be answered (*Vavilov* at paras. 81 and 86) and the decision fails on both the transparency and justification metrics.
>
> [*Canada (Attorney General) v. Robinson*, 2022 FCA 59, at para. 28 [*Robinson*].]

[41] As a corollary of this, a decision maker is not required to address the *Charter* in every decision (*Loyola*, at para. 4). A decision maker's obligation to address *Charter* interests can be no greater than the *Charter* interests themselves. As noted by this Court in *Robinson*, regard must be had to context and whether the circumstances call for an answer.

[42] The purpose of section 7 is to protect against the "deprivation" by the government of a life, liberty or security interest. There is no deprivation here; rather, the HCPs' asserted *Charter*

interests arise only because they have asked for the right to possess a controlled substance. They have voluntarily chosen to put themselves in jeopardy.

[43] The appellants rely heavily on *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 (*PHS*). In *PHS*, health care providers operated a government-sanctioned safe injection site and, by reason of that, could face prosecution under section 4 for carrying out their duties (at paras. 87, 101). Absent an exemption, the site could not continue, and the health care providers could not offer medical care.

[44] The circumstances in this case are far removed from those in *PHS*. The appellants are not engaged or retained to deliver a sanctioned medical service and consumption and possession of psilocybin is not required as part of the HCPs' duties. As the Minister noted, the HCPs can offer PSAP without experiential training. The Minister disagreed with the proposition that experiential training resulted in safer or more effective care.

[45] Reliance is also put on *R. v. Parker*, 2008 FC 33 (*Parker*), which dealt with the consumption of marijuana for medical purposes. Again, there are key points of distinction between *Parker* and the case before us. In *Parker*, the section 7 issue was adjudicated on a factual finding that there was an established medical need for cannabis for the treatment of the applicant's own medical condition. In this case, those with a medical condition have not applied for an exemption.

[46] Nor can the HCPs be the torch bearers or proxies of the section 7 interests of third parties who may, someday, be their patients. They cannot inflate their own section 7 interests in immunity from prosecution under section 4 of the CDSA by pointing to the section 7 interests of the patient appellants. *Charter* rights are personal and can only be claimed by the person whose right has been infringed or denied.

[47] While it is beyond dispute that section 7 protects the ability of a person to make reasonable medical choices without fear of criminal sanction, the HCPs' professional interest in becoming better health care providers and to deliver "optimum results" is not a recognized *Charter* right. To draw an analogy, cancer patients could argue that the government should establish more residency positions in oncology, so that there will be a greater pool of qualified oncologists to respond to the section 7 interests of cancer patients. Courts have consistently rejected the argument that section 7 compels Ministerial discretion to be exercised to give effect to what might be characterized as positive rights (*Auton (Guardian ad litem of) v. British Columbia (Attorney General)*, 2004 SCC 78; *Cambie Surgeries Corporation v. British Columbia (Attorney General)*, 2022 BCCA 245).

[48] There was evidence before the Minister that HCPs do not *need* experiential training to appreciate what the patient experiences, and that patient appellants undergoing PSAP do not need to be treated or assisted by HCPs who themselves have experiential training. Apart from one letter, affixed as an exhibit to an affidavit, by one HCP who had undergone experiential training and found it beneficial, the balance of the evidence did not support the view that PSAP delivered by an HCP who has gone through TheraPsil's training programs (or similar programs)

will be more effective. As the Federal Court judge noted, the HCPs' exemption requests stated that "for optimal results" qualified practitioners should have experience with psilocybin. There is nothing that suggests that TheraPsil's training program is mandated by either Health Canada or provincial regulatory bodies. As the Federal Court stated, "the foundation for the *Charter* arguments is not supported by the evidence" (Reasons, at para. 100).

[49] In this case, the *Charter* argument arises in the context of a narrow, specific question in an emerging field of medical science. The Minister founded her Decisions on certain facts and certain reasonably-held opinions that, in essence, disagreed with the factual premise that underlies the appellants' *Charter* arguments. Pallotta J. found that the Minister addressed the *Charter* arguments implicitly "by addressing their very foundation, which is that [HCPs] need experiential training to provide the most safe and effective care to patients" (Reasons, at para. 112). I agree.

[50] An administrative decision maker need not expressly decide whether a *Charter* right is engaged by a decision and, if so, how it is balanced (*Vavilov*, at paras. 9, 91, 94); rather the core question is, in taking into account the nature of the decision and the statutory and institutional context, whether the decision reflects a proportionate balancing of the *Charter* interests (*Doré*, at paras. 57, 58, 63).

[51] Although the *Charter* values in question (immunity from prosecution and a right to a certain course of medical treatment), were not articulated or expressed in such terms, the Decisions nevertheless reflect the balancing of interests that the *Doré/Loyola/TWU* framework

requires. The Decisions note the potential health and safety risks associated with consuming illegally-sourced psilocybin, the prevention of which is one of the objectives of the CDSA. I note in particular the "Summary Report – Psychedelics: Clinical Use and Risks", which was before the Minister at the time:

> **41.** In addition to the foregoing risks of using psilocybin, there are particular risks associated with the dosing of illegally-obtained psilocybin, as follows:
>
> > Unlike clinical studies using pharmaceutical grade psilocybin and accompanying medical personnel, it is challenging to estimate dose when consuming mushrooms. The strength of magic mushrooms can vary greatly. One mushroom may have different concentrations of the active ingredients compared to another and consequently the effects of the magic mushroom can depend on the dose and type of mushroom used (Cunningham, 2008; Hasler, 2004; van Amsterdam, 2011).

[52] The same document, under the heading "Potential harms from Psychedelics," also advises that consumption may cause increased blood pressure and heart rate, heart palpitations, nausea and vomiting, sleep disorder, fatigue and migraines. It cautions that, for individuals with existing mental health conditions, there is an elevated risk of side effects, including psychosis.

[53] There is, therefore, a direct connection between the public health objectives of the CDSA and the consideration of the interests of the appellants (*TWU*, at para. 5; *Canada (Attorney General) v. Bedford*, 2013 SCC 72, at para. 111). Turning to overbreadth, in *R. v. Malmo-Levine*, 2003 SCC 74 the Supreme Court of Canada held that a prohibition on the recreational use of controlled substances was not arbitrary where the claimants had failed to establish a need for personal consumption. That is the case here.

[54] *Lance* was decided after the Federal Court's judgment was issued in these proceedings and prior to this appeal. In *Lance*, Fothergill J. found the Minister's decision to deny a patient access to psilocybin through the Special Access Program unreasonable, in part due to the Minister's failure to engage with the applicant's section 7 *Charter* arguments. The applicant's "invocation of the Charter was intended to assist in overcoming [the] potential obstacles [to his Special Access Program request]," including the availability of lawful alternatives and the inconclusiveness of the science relating to the use of psilocybin in his condition (*Lance*, at para. 89). *Lance* bears no similarly to this case, if only by reason of the fact that the applicant in *Lance* applied for his own exemption under a different regulatory pathway.

[55] Finally, the Decisions do not prevent a person with an established and reasonable medical need from accessing psilocybin, nor do they prevent an HCP from providing PSAP. The Decisions note these alternative pathways to access.

[56] To conclude, the obligation to address the *Charter* arguments can be no greater than the nature of the *Charter* interests themselves. The Decisions do not engage the section 7 interests of the HCPs nor the patient appellants and therefore there was no requirement that they be expressly addressed. I would add that even if they were engaged, the Decisions reflect a proportionate balancing of considerations consistent with the *Doré /Loyola/TWU* framework.

Reasonableness of the Decisions

[57] The Minister denied the requests on the basis that:

> "…there is an option available under the [FDR] through which the sale of the drug for the purposes of a clinical trial may be authorized, and therefore, an exemption under the [CDSA] is not necessary."

[58] The Decisions explain that a clinical trial would provide the legal protection sought by the HCPs and mitigate the health and safety risks associated with the consumption of psilocybin. An approved clinical trial would authorize the sale of psilocybin under Part J of the FDR regulations, promulgated pursuant to subsection 55(1) of the CDSA, constituting an "authorization under the regulations" for the purposes of subsection 4(1) of the Act.

[59] The appellants say that the Decisions do not conform to the *Vavilovian* standards of reasonableness. They raise three deficiencies.

[60] The appellants contend that the existence of a clinical trial or other regulatory option does not preclude an exemption being granted in the public interest under subsection 56(1). They argue that the Minister effectively fettered her discretion by holding that a clinical trial precluded an exemption from being granted in the public interest.

[61] The appellants also contend that the Minister unreasonably concluded that exemptions carried unacceptable risks and erroneously concluded that a clinical trial would reduce those risks. They say that a clinical trial is not compatible with TheraPsil's training objectives, is not available in a timely manner and, as the effects of psilocybin are already known, it would be unethical to conduct a clinical trial for therapist training without a specific research question.

[62] The third challenge to the Decisions is that they are inconsistent with decisions rendered two years earlier.

[63] I would reject the first two grounds, but accede to the third.

[64] In 2020, Health Canada granted 19 substantively identical subsection 56(1) exemption requests for HCPs to possess and consume psilocybin-containing mushrooms for the purpose of completing TheraPsil's experiential training. At the time, Health Canada characterized the requests as "not medical or scientific exemption requests" but rather requests "otherwise in the public interest" under subsection 56(1). This is unsurprising as the 2020 requests were made for educational purposes, not to treat applicants' medical conditions or to generate scientific data for research.

[65] I begin with the argument that the Decisions are unreasonable as they do not respond to the HCPs' concerns about the utility and viability of a clinical trial.

[66] TheraPsil states that it operates as a not-for-profit organization and does not have the resources or capacity to sponsor its own trial, that the significant time required to organize a clinical trial perpetuates patient suffering and that its training purposes are incompatible with the experimental design of a clinical trial. Ethically, the appellants say that a clinical trial cannot be conducted for the purpose of therapist training because the "Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans" requires a valid research

question, dissuades clinical trials for commercial purposes and requires that trials are grounded in *bona fide* scientific purpose, which is not possible given their educational training purpose.

[67] I find the Decisions respond to these concerns, albeit somewhat obliquely but sufficiently that the reasoning is clear.

[68] The Minister rejected the proposition that a clinical trial would be unethical because there cannot be a clinical trial on an issue in respect of which there is a scientific consensus and gave reasons for so doing. The Minister was of the opinion that the scientific literature did not demonstrate that experiential training was necessary for HCPs to treat patients and HCPs can provide PSAP without experiential training.

[69] There is a fundamental divergence between the Minister and the appellants on this key question. TheraPsil says that there is no scientific uncertainty about the need for experiential training. The Minister disagrees.

[70] The appellants submitted evidence in favour of experiential training as a best practice in the form of three peer-reviewed journal articles, letters from HCPs and academics in the field of psychedelic therapy and affidavits from patients. The requests stated that TheraPsil's training program is modeled after the Multidisciplinary Association for Psychedelic Studies (MAPS) protocol. MAPS are American clinical investigations involving experientially trained HCPs, approved by the United States Food and Drug Administration, which study the medicinal effects of psychedelics.

[71] The Minister rejected this evidence as not "fall[ing] high on the evidence pyramid hierarchy," noting that she is "not aware of peer-reviewed clinical evidence to demonstrate that [HCPs] need to take a psychedelic drug in order to appreciate what the patient experiences." The Decisions also state that HCPs do not require experiential training to provide PSAP, and that this is a requirement imposed by TheraPsil's training program.

[72] The clinical trial pathway does not need to satisfy TheraPsil's training protocol or mirror TheraPsil's training program. Given the Minister's view that experiential training was not necessary for PSAP, the HCPs' arguments based on the clinical trial's incompatibility with TheraPsil's training program fall away, premised as they were on a proposition that the Minister reasonably rejected.

[73] I turn next to the argument that the Minister fettered her discretion.

[74] The Decisions state that "exemptions under subsection 56(1) of the CDSA are granted on an exceptional basis when other legal regulatory options for access are not available." The appellants argue that the Minister fettered her discretion by limiting subsection 56(1) to situations where there are no other regulatory options for access.

[75] I agree that, on face value, this appears to be a fettering of discretion. Nothing in the plain text and purpose of subsection 56(1) supports such a limitation. In *PHS*, McLachlin C.J.C. noted that "[t]he Minister cannot simply deny an application for a s. 56 exemption on the basis of *policy simpliciter*" (*PHS*, at para. 128). It is clear that the Minister has a policy, namely that

individual exemptions will not be granted in circumstances where there are other means of access, either through a clinical trial or the Special Access Program.

[76] However, on a fair reading of the Decisions, it is apparent that the Minister considered and disposed of the requests based on her assessment of the public interest. Put otherwise, I understand the Decisions to be that, given the existence of a regulatory route by which the HCPs could gain access, it was not in the public interest to grant the exemptions.

[77] The requests were not framed as requests for a "medical or scientific purpose"; rather, the purpose of the exemptions was to provide optimum training for the HCPs. The Decisions themselves consider the requests to be motivated "for training" purposes. The training motivation that underlies the requests is mentioned several times in the course of the Decisions. Given that the exemptions were not sought for medical or scientific purposes, the only remaining criteria is that of the public interest.

[78] I cannot accept the argument that the Minister fettered her discretion by concluding that the existence of a regulatory option foreclosed consideration of whether it would be in the public interest to grant the exemptions. The Decision gives reasons why a clinical trial is preferred over an exemption.

[79] The Decisions note that there are health and safety risks associated with obtaining and consuming illegally-sourced psilocybin (the appellants did not disclose the source from which they would procure the psilocybin), and that a clinical trial offers greater protection to the HCPs

"by ensuring that the substance that is obtained complies with [good manufacturing practices] and is administered in accordance with national and international ethical, medical and scientific standards." The Decisions also state:

> Further, we have held multiple conversations, over the past 2 years, with your supporting organization TheraPsil on the same subject. The message conveyed was clear, exemptions under subsection 56(1) of the CDSA are granted on an exceptional basis when other legal regulatory options for access are not available.

[80] I agree with the appellants that the Decisions could be understood to be stating an invariable rule. Were that the case, it would constitute an improper fettering of discretion. Here, however, the reasons, when read globally, reveal a reasoned consideration of why it was not in the public interest to grant an exemption and the corresponding advantages of a clinical trial. While the result may not align with the appellants' objectives, they nonetheless provide an explanation as to why the Minister has channelled their request away from a section 56 exemption to a clinical trial.

[81] *Vavilov* teaches that the legal and factual constraints bearing on a decision maker inform a reviewing court's assessment of the reasonableness of a decision; the decision maker's authorizing legislation is particularly relevant (at paras. 106, 108). Here, the exemption requests were submitted pursuant to subsection 56(1) of the CDSA, the Minister's empowering legislation. In applying this provision, the Minister must "consider whether denying an exemption would cause deprivations of life and security of the person that are not in accordance with the principles of fundamental justice"; balancing the dual public health and public safety objectives of the CDSA guides the Minister in this analysis (*PHS*, at paras. 152-153).

[82] Subsection 56(1) endows the Minister with a broad discretion, underscored by the words "opinion" and "public interest" in the provision, to grant exemptions, echoing the Supreme Court of Canada in *PHS* (at para. 39):

56 (1) The Minister may, on any terms and conditions that the Minister considers necessary, exempt from the application of all or any of the provisions of this Act or the regulations any person or class of persons or any controlled substance or precursor or any class of either of them if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.	**56 (1)** S'il estime que des raisons d'intérêt public, notamment des raisons médicales ou scientifiques, le justifient, le ministre peut, aux conditions qu'il estime nécessaires, soustraire à l'application de tout ou partie de la présente loi ou de ses règlements toute personne ou catégorie de personnes, ou toute substance désignée ou tout précurseur, ou toute catégorie de ceux-ci.

This language gives effect to the CDSA's purpose of balancing the competing interests of public safety and public health (*PHS*, at para. 20).

[83] I have explained why this case is different from *PHS*. The only *Charter* interest that is in play here is that of the potential prosecution of the HCPs – a prosecution that would only arise from the HCPs' voluntarily choosing to possess and consume psilocybin. They are not in the same position as the medical staff running the Insight clinic in *PHS* who, in the course of conducting their lawful duties, ran the risk of prosecution.

[84] I see no reviewable error in the Minister's assessment of the public interest.

[85] This leaves the third challenge to the reasonableness of the Decisions – their inconsistency with the 2020 grant of 19 exemptions.

[86] The 2020 exemptions were granted to HCPs on the basis that there were problems with clinical trials such that personal exemptions were the preferred pathway. In 2020, the Minister said that the experts were of the view that experiential training was preferrable for successful PSAP. In 2022, the Minister held the view that there was no expert consensus and that clinical trials were preferable. Significant policy shifts such as this require explanation where they affect individual interests.

[87] In 2020, Health Canada did not require peer-reviewed clinical studies for its approval of exemption requests, nor did it consider TheraPsil's requirement for experiential training a factor that precluded approval. At the time, Health Canada stated that "[t]he experts that have been consulted…have strongly indicated that personal experience with psilocybin is required in order to safely guide patients through treatment sessions." In the memorandum to the Minister regarding the notices of intent, Health Canada indicated that the 2020 exemptions were granted "on the view that the HCPs delivering [PSAP] to individual patients who received an exemption should also be trained in this area of psychotherapy to improve their knowledge and guide the patients." I also note that Health Canada was aware, in 2020, of the MAPS, citing them in its materials.

[88] In August 2020, the Office of Clinical Trials was of the view that "a clinical trial [was] not possible for the situation TheraPsil is requesting" and were quite specific about the reasons;

concerns about physicians treating themselves or self-prescribing controlled drugs, the need for practitioners to refrain from treating patients until they themselves had no more drug in their system, a preference for synthetic psilocybin to control potency and dosage, and concerns that it would be unethical for HCPs to switch from observers to participants unless they themselves suffered from the same condition as the patients. Health Canada's revised position in 2022 is that clinical trials under the FDR are "the most appropriate pathway that allows participants to access products that are experimental and protects the best interests of participants."

[89] Some additional inconsistencies are worth mentioning. The 2020 exemptions were granted for HCPs to possess and consume psilocybin-containing mushrooms, not synthetic psilocybin. At the time, Health Canada considered these exemptions to be "the complementary piece to the patient-specific psilocybin exemptions that have been issued," and has continued granting individual exemptions for patients to consume and possess psilocybin-containing mushrooms for medicinal purposes (see *Lance*). The Minister's 2022 position is that a clinical trial would ensure that synthetic psilocybin is prepared in compliance with good manufacturing practices. One of the responsibilities of public office is that decision makers approach each decision with an open mind and assess the matter on its own merits. However, where, as here, there is a shift in policy or a change in the assessment of the underlying evidence, science or facts, it is incumbent on the Minister to explain the change. This is the justificatory burden that *Vavilov* addresses, this is what transparency means in judicial review.

[90] These inconsistencies in the Minister's position in 2020 and her position in 2022, including the importance of experiential training for HCPs, the propriety of a clinical trial, and the evidentiary requirements for a subsection 56(1) exemption are not resolved in the Decisions.

[91] It is a truism that science does not stand still, and decision makers engaged with science are not expected to stand still either—and hopefully they never will—rather, they make their decisions in real time based on the evidence before them. If the Minister, in 2022, takes a more granular look at the evidence than it did in 2020, or weighs relevant considerations differently, that alone does not make the decision unreasonable.

[92] The Decision letters acknowledge that this is a change in the Minister's position. The Minister describes the change as "an evolution" in the Office of Clinical Trial's position (Reasons, at para. 68). This is self-evident. But it is a conclusion, not an explanation, and the focus of judicial review is intelligibility, justification and transparency in decision-making.

[93] The Decisions note that a total of eleven clinical trials have since been authorized and that $3 million in funding is now available to evaluate the use of psilocybin in the treatment of mental health and substance use disorders. These developments could explain the policy shift, but the Court would be inferring or speculating that this was the case. Courts can "connect the dots on the page where the lines, and the direction they are headed" are obvious (*Vavilov*, at para. 97 citing *Komolafe v. Canada (Citizenship and Immigration)*, 2013 FC 431, at para. 11).

[94] It would be an uncomfortable stretch of judicial reasoning to connect the dots here. The shift in policy between 2020 and 2022 and the Minister's appreciation of the relevant factors are significant, if not abrupt, and call for some explanation. This is a critical part of the Decisions, and it is the role of the Minister and not the Court to make the required connections.

[95] Though, as I have already explained, neither the section 7 rights of the patient appellants or the HCPs are engaged, I see no principled reason why the words of McLachlin C.J.C. in *PHS,* that "[t]he Minister cannot simply deny an application for a s. 56 exemption on the basis of *policy simpliciter*," do not also apply from an administrative law perspective (at para. 128). In 2020, the Minister was satisfied that subsection 56(1) exemption requests should be granted to HCPs for PSAP training purposes as a matter of public interest. It was incumbent on the Minister to explain why the nearly identical exemption requests at issue in this case were no longer in the public interest, but a clinical trial was. The Decisions do not provide this explanation, and thus failed to demonstrate the necessary transparency for a reasonable decision under *Vavilov*. I am not satisfied that the justificatory burden has been met, and would allow the appeal on this basis.

Conclusion

[96] At their core, the first two of the appellants' attacks on the reasonableness of the Decisions are invitations for the Court to adjudicate a matter of medical debate: whether experiential training is necessary for successful PSAP. The appellants say that it is, the Minister disagrees and says a clinical trial is to be preferred. The appellants challenge this position by pointing to the limitations of a clinical trial.

[97] They say that, in disagreeing, the Minister did not "grapple", to use a now much over-used phrase, with the appellants' position. I do not agree. Grappling does not mean acceding. The Minister may reasonably disagree and, on this point, for the reasons given, I find that the Decisions meet the *Vavilovian* standard. They fail, however, to explain the shift in policy.

[98] I would therefore allow the appeal and set aside the Decisions. I would remit the exemption requests to the Minister for redetermination in accordance with these reasons. As agreed between the parties, costs are awarded to the appellants in this Court and below, in the all-inclusive amount of $12,500.

[99] Before concluding, I wish to commend counsel on the exceptional quality of the Appeal Book. It was a pleasure to work with - exquisitely organized, hyperlinked, tabbed, and easy to navigate notwithstanding its formidable length. This quality of practice is not always seen and stands as a good example to the bar.

"Donald J. Rennie"
J.A.

"I agree.
Judith Woods J.A."

"I agree.
J.B. Laskin J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-290-23
STYLE OF CAUSE:	JEFF TOTH *et al.* v. MINISTER OF MENTAL HEALTH AND ADDICTIONS AND ASSOCIATE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	NOVEMBER 6, 2024
REASONS FOR JUDGMENT BY:	RENNIE J.A.
CONCURRED IN BY:	WOODS J.A. LASKIN J.A.
DATED:	JUNE 18, 2025

APPEARANCES:

Nicholas Pope	FOR THE APPELLANTS
Jennifer Francis Brooklynne Eeuwes	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Hameed Law Ottawa, Ontario	FOR THE APPELLANTS
Shalene Curtis-Micallef Deputy Attorney General of Canada	FOR THE RESPONDENT